

S/N Unknown

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: John F. Engelhardt et al.

Examiner: Unknown

Serial No.: Unknown

Group Art Unit: Unknown

Filed: Herewith

Docket: 875.007US2

Title: ADENO-ASSOCIATED VIRUS VECTORS

11000 U.S. PTO  
10/054665  
01/22/02



**INFORMATION DISCLOSURE STATEMENT**

#8

Commissioner for Patents  
Washington, D.C. 20231

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the enclosed materials are brought to the attention of the Examiner for review in connection with the above-identified patent application. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants.

In accordance with 37 C.F.R. § 1.98(d), copies of the listed documents are not provided as these references were previously cited by or submitted to the U.S. Patent Office in connection with Applicants' prior U.S. application, Serial No. 09/276,625, filed on March 25, 1999, which is relied upon for an earlier filing date under 35 U.S.C. §120.

Applicants respectfully request consideration of these references during prosecution of the above-identified matter. The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this communication.

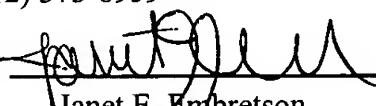
Respectfully submitted,

JOHN F. ENGELHARDT ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. Box 2938  
Minneapolis, MN 55402  
(612) 373-6959

Date JANUARY 22, 2002

By 

Janet E. Embretson

Reg. No. 39,665

"Express Mail" mailing label number: EV 041 073 515 US

Date of Deposit: January 22, 2002

This paper or fee is being deposited on the date indicated above with the United States Postal Service pursuant to 37 CFR 1.10, and is addressed to the Commissioner for Patents, Box Patent Application, Washington, D.C. 20231.

Form 1449*	Atty. Docket No.: 875.007US2	Serial No. Unknown
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	
	Applicant: John F. Engelhardt et al.	Filing Date: Herewith
		Group: Unknown

5  
1000  
J 10/05/965  
10/05/965  
01/23/01

## U. S. PATENT DOCUMENTS

**Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	5,691,176	11/25/1997	Lebkowski, J.S., et al.	435	172.3	06/02/95
	6,083,702	07/04/2000	Mitchell, L.G., et al.	435	6	08/13/98
	6,200,560	03/13/2001	Couto, L.B., et al.	424	93.2	12/22/99

## FOREIGN PATENT DOCUMENTS

**Examiner Initial	Document Number	Date	Country	Class	Subclass	Translation Yes	Translation No
	94/13788	12/04/1992	PCT	C12N	7/01		
	95/07351	09/10/1993	PCT	C12N	15/10		
	97/22250	12/13/1996	PCT	A01N	43/04		
	98/09657	09/06/1996	PCT	A61K	48/00		

## OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

	Afione, S.A., et al., "In Vivo Model of Adeno-Associated Virus Vector Persistence and Rescue", <u>Journal of Virology</u> , 70 (5), pp. 3235-3241, (May 1996)
	Ali, R.R., et al., "Gene transfer into the mouse retina mediated by an adeno-associated viral vector", <u>Human Molecular Genetics</u> , 5 (5), pp. 591-594, (1996)
	Bennett, J., et al., "Real-Time, Noninvasive In Vivo Assessment of Adeno-Associated Virus-Mediated Retinal Transduction", <u>Investigative Ophthalmology &amp; Visual Science</u> , 38 (13), pp. 2857-2863, (Dec. 1997)
	Berns, K.I., "Parvovirus Replication", <u>Microbiological Reviews</u> , 54 (3), pp. 316-329, (Sept. 1990)
	Berns, K.I., et al., "Biology of Adeno-associated Virus", <u>In: Current Topics in Microbiology and Immunology</u> , 218, Springer-Verlag, Berlin: R.W. Compans, et al., (Eds.), pp. 1-23, (1996)
	Clark, K.R., et al., "Recombinant Adeno-Associated Viral Vectors Mediate Long-Term Transgene Expression in Muscle", <u>Human Gene Therapy</u> , 8, pp. 659-669, (April 10, 1997)
	Conrad, C.K., et al., "Safety of single-dose administration of an adeno-associated virus (AAV)-CFTR vector in the primate lung", <u>Gene Therapy</u> , 3, pp. 658-668, (1996)

Examiner	Date Considered
----------	-----------------

\*Substitute Disclosure Statement Form (PTO-1449)

\*\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 875.007US2	Serial No. Unknown
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant: John F. Engelhardt et al.	
	Filing Date: Herewith	Group: Unknown

## OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

\*\*Examiner  
Initial

Duan, D., et al., "Circular intermediates of recombinant adeno-associated virus having defined structural characteristics responsible for long-term episomal persistence in muscle tissue", <u>J. of Virology</u> , 72 (11), pp. 8568-8577, (Nov. 1998)
Duan, D., et al., "Formation of adeno-associated virus circular genomes is differentially regulated by adenovirus E4 ORF6 and E2a gene expression", <u>J. Virology</u> , 73 (1), pp. 161-169, (Jan. 1999)
Duan, D., et al., "Polarity Influences the Efficiency of Recombinant Adenoassociated Virus Infection in Differentiated Airway Epithelia", <u>Human Gene Therapy</u> , 9, pp. 2761-2776, (Dec. 10, 1998)
Duan, D., et al., "Structural Analysis of adeno-associated virus transduction circular intermediates", <u>Virology</u> , 261 (1), pp. 8-14, (Aug. 1999)
Duan, D., et al., "Structural and functional heterogeneity of integrated recombinant AAV genomes", <u>Virus Research</u> , 48 (1), pp. 41-56, (Jan. 1997)
Fisher, K., et al., "Recombinant adeno-associated virus for muscle directed gene therapy", <u>Nature Medicine</u> , 3 (3), pp. 306-312, (March 1997)
Fisher-Adams, G., et al., "Integration of Adeno-Associated Virus Vectors in CD34+ Human Hematopoietic Progenitor Cells After Transduction", <u>Blood</u> , 88 (2), pp. 492-504, (July 15, 1996)
Flotte, T.R., et al., "Adeno-Associated Virus Vector Gene Expression Occurs in Nondividing Cells in the Absence of Vector DNA Integration", <u>American Journal of Respiratory Cell and Molecular Biology</u> , 11, pp. 517-521, (1994)
Giraud, C., et al., "Recombinant junctions formed by site-specific integration of adeno-associated virus into an episome", <u>J. of Virology</u> , 69 (11), pp. 6917-6924, (Nov. 1995)
Halbert, C.L., et al., "Transduction by Adeno-Associated Virus Vectors in the Rabbit Airway: Efficiency, Persistence, and Readministration", <u>Journal of Virology</u> , 71 (8), pp. 5932-5941, (Aug. 1997)

Examiner \_\_\_\_\_ Date Considered \_\_\_\_\_

\*Substitute Disclosure Statement Form (PTO-1449)

\*\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 875.007US2	Serial No. Unknown
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	
	Applicant: John F. Engelhardt et al.	Filing Date: Herewith
		Group: Unknown

## OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

\*\*Examiner  
Initial

Herzog, R.W., et al., "Stable gene transfer and expression of human blood coagulation factor IX after intramuscular injection of recombinant adeno-associated virus", <u>PNAS</u> , 94, pp. 5804-5809, (May 1997)
Kaplitt, M.G., et al., "Long-term gene expression and phenotypic correction using adeno-associated virus vectors in the mammalian brain", <u>Nature Genetics</u> , 8, pp. 148-154, (Oct. 1994)
Kearns, W.G., et al., "Recombinant adeno-assicated virus (AAV-CFTR) vectors do not integrate in a site-specific fashion in an immortalized epithelial cell line", <u>Gene Therapy</u> , 3, pp. 748-755, (1996)
Kessler, P.D., et al., "Gene delivery to skeletal muscle results in sustained expression and systemic delivery of a therapeutic protein", <u>PNAS</u> , 93, pp. 14082-14087, (Nov. 1996)
Kotin, R.M., et al., "Characterization of a preferred site on human chromosome 19q for integration of adeno-associated virus DNA by non-homologous recombination", <u>The EMBO Journal</u> , 11 (13), pp. 5071-5078, (1992)
Linden, R.M., et al., "Site-specific integration by adeno-associated virus", <u>PNAS</u> , 93, pp. 11288-11294, (Oct. 1994)
Linden, R.M., et al., "The recombinant signals for adeno-assicated virus site-specific integration", <u>PNAS</u> , 93, pp. 7966-7972, (July 1996)
McLaughlin, S.K., et al., "Adeno-associated virus general transduction vectors: analysis of proviral structures", <u>Journal of Virology</u> , 62 (6), pp. 1963-1973, (June 1988)
Muzyczka, N., "Use of Adeno-Associated Virus as a General Transduction Vector for Mammalian Cells", In: <u>Current Topics in Microbiology and Immunology</u> , 158, Springer-Verlag, Berlin: R.W. Compans, et al., (Eds.), pp. 97-129, (1992)
Ponnazhagan, S., et al., "Lack of Site-Specific Integration of the Recombinant Adeno-Associated Virus 2 Genomes in Human Cells", <u>Human Gene Therapy</u> , 8, pp. 275-284, (Feb. 10, 1997)
Puttaraju, M., et al., "Spliceosome-mediated RNA trans-splicing as a tool for gene therapy", <u>Nature Biotechnology</u> , 17 (3), pp. 246-252, (March 1999)

Examiner	Date Considered
----------	-----------------

\*Substitute Disclosure Statement Form (PTO-1449)

\*\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 875.007US2	Serial No. Unknown
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)</b>	Applicant: John F. Engelhardt et al.	
	Filing Date: Herewith	Group: Unknown

**OTHER DOCUMENTS**

(Including Author, Title, Date, Pertinent Pages, Etc.)

**\*\*Examiner  
Initial**

Qing, K., et al., "Adeno-Associated Virus Type 2-Mediated Gene Transfer: Correlation of Tyrosine Phosphorylation of the Cellular Single-Stranded D Sequence-Binding Protein with Transgene Expression in Human Cells In Vitro and Murine Tissues In Vivo", <u>Journal of Virology</u> , 72 (2), pp. 1593-1599, (Feb. 1998)
Qing, K., et al., "Human fibroblast growth factor receptor 1 is a co-receptor for infection by adeno-associated virus 2", <u>Nature Medicine</u> , 5 (1), pp. 71-77, (Jan. 1999)
Qing, K., et al., "Role of tyrosine phosphorylation of a cellular protein in adeno-associated virus 2-mediated transgene expression", <u>PNAS</u> , 94, pp. 10879-10884, (Sept. 1997)
Ramage, A.D., et al., "Improved EBV-based shuttle vector system: dicistronic mRNA couples the synthesis of the Epstein-Barr nuclear antigen-1 protein toneomycin resistance", <u>Gene</u> , 197 (102), pp. 83-89, (1997)
Samulski, R.J., "Adeno-assicated virus: integration at a specific chromosomal locus", <u>Current Opinion in Genetics &amp; Development</u> , 3 (1), pp. 74-80, (1993)
Samulski, R.J., et al., "A Recombinant Plasmid from Which an Infectious Adeno-Associated Virus Genome Can Be Excised In Vitro and Its Use To Study Viral Replication", <u>Journal of Virology</u> , 61 (10), pp. 3096-3101, (Oct. 1987)
Samulski, R.J., et al., "Helper-Free Stocks of Recombinant Adeno-Associated Viruses: Normal Integration Does Not Require Viral Gene Expression", <u>Journal of Virology</u> , 63 (9), pp. 3822-3828, (Sept. 1989)
Snyder, R.O., et al., "Persistent and therapeutic concentrations of human factor IX in mice after hepatic gene transfer of recombinant AAV vectors", <u>Nature Genetics</u> , 16, pp. 270-276, (July 1997)
Summerford, C., et al., "alphaVbeta5 integrin: a co-receptor for adeno-associated virus type 2 infection", <u>Nature Medicine</u> , 5 (1), pp. 78-82, (Jan. 1999)
Summerford, C., et al., "Membrane-Associated Heparan Sulfate Proteoglycan Is a Receptor for Adeno-Associated Virus Type 2 Virions", <u>Journal of Virology</u> , 72 (2), pp. 1438-1445, (Feb. 1998)
Walsh, C.E., et al., "Phenotypic Correction of Fanconi Anemia in Human Hematopoietic Cells with a Recombinant Adeno-associated Virus Vector", <u>The Journal of Clinical Investigation</u> , 94 (4), pp. 1440-1448, (Oct. 1994)

Examiner	Date Considered
----------	-----------------

\*Substitute Disclosure Statement Form (PTO-1449)

\*\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form 1449*	Atty. Docket No.: 875.007US2	Serial No. Unknown
	Applicant: John F. Engelhardt et al.	
	Filing Date: Herewith	Group: Unknown

**INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT**  
(Use several sheets if necessary)

**OTHER DOCUMENTS**

(Including Author, Title, Date, Pertinent Pages, Etc.)

**\*\*Examiner  
Initial**

Westfall, T.D., et al., "The ecto-ATPase inhibitor ARL 67156 enhances parasympathetic neurotransmission in the guinea-pig urinary bladder", <u>European Journal of Pharmacology</u> , 329, pp. 169-173, (1997)
Wu, P., et al., "Adeno-Associated Virus Vector-Mediated Transgene Integration into Neurons and Other Nondividing Cell Targets", <u>Journal of Virology</u> , 72 (7), pp. 5919-5926, (July 1998)
Xiao, X., et al., "Efficient long-term gene transfer into muscle tissue of immunocompetent mice by adeno-associated virus vector", <u>J. of Virology</u> , 70 (11), pp. 8098-8108, (Nov. 1996)

Examiner	Date Considered
----------	-----------------

\*Substitute Disclosure Statement Form (PTO-1449)

\*\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.